

Fergus Cochrane
Clerk to the Public Petitions Committee
TG.01
The Scottish Parliament

Edinburgh
EH99 1SP

Reference: FAS/0034

5 January 2011

Dear Mr Cochrane

CONSIDERATION OF PETITION PE1376

I refer to your letter to the Food Standards Agency in Scotland dated 8 December. I am pleased to reply to your letter - our response covers the interests of the Agency as a whole.

In his petition Mr McDonald refers to the Food Standards Agency and the Scottish Food Advisory Committee. For clarity:

The Agency is a non-ministerial government department operating at arms length from ministers. It is governed by a Board appointed to act in the public interest. Our policy remit relates to food and feed safety and standards and is wholly devolved. In this context for the delivery of its functions the Agency has responsibilities to the Westminster and devolved administrations.

The role of the Scottish Food Advisory Committee is to:

- Offer information and advice on issues relating to the protection of public health in Scotland in relation to food, taking into account the advice of other independent advisory committees working in the food safety and standards area and focussing in particular on Scottish circumstances.
- Consider the Agency Board's proposals for activities from a Scottish perspective and offer advice on particular Scottish food safety and standards priorities.

In Scotland, the Food Standards Agency Scotland has a responsibility to protect consumers with regard to food safety including the safety of food additives such as aspartame.

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Issues raised in the petition

The Agency does not support the Petition.

Legislation on food additives including sweeteners such as aspartame is harmonised across the EU. Food additives are only authorised following extensive safety testing.

The safety information on aspartame has been extensively reviewed by not only the Committee On Toxicity of Chemicals in Food, Consumer products and the Environment (COT), but also the European Food Safety Authority and the Joint FAO/WHO Expert Committee on Food Additives, an international scientific expert committee that is administered jointly by the Food and Agriculture Organization of the United Nations and the World Health Organization. Aspartame is approved for use not only in the UK but across the EU and in many other countries across the world.

The Agency agrees with the Petitioner that when aspartame is metabolised one of the breakdown products is methanol. However, we do not agree on the toxicological significance of this. The extensive body of evidence available shows the body can safely metabolise the amount of methanol produced from the breakdown of aspartame as well as that produced from consuming fruits and vegetables and their juices and from legitimate alcoholic beverages. Annex 1 provides details on the natural occurrence of methanol in the diet and the ability of the body to safely metabolise this.

Dietary methanol was not thought to be a problem but in light of consumer concerns, including those of the Aspartame Awareness Campaign, the COT agreed that it would be worthwhile to review the available data on the chronic toxicity of methanol. The COT has since produced a draft statement, publically available at the link below:

<http://cot.food.gov.uk/pdfs/tox201038.pdf>

The conclusion in the draft statement is that exposure to methanol at the levels found in the diet both naturally occurring and from currently permitted levels of aspartame would not be expected to result in adverse effects.

The final text of the COT statement has yet to be confirmed. The Petitioner has offered comments on the COT evaluation and these are currently being considered by COT.

Issues raised during the discussion of the petition

Our reply to the comment relating to how the body metabolises methanol is covered by our response to issues raised in the petition

Written questions:

What is your response to the petition and do you support what the petitioner is calling for?

This question is addressed in our response to the issues raised in the petition

What actions need to be taken by government on the use of free methanol?

There is no evidence of health concerns with the currently permitted levels of aspartame. The current work by COT needs to be considered when it is complete and there is an ongoing need to review any new relevant properly accredited scientific information as it becomes available.

I hope the above has addressed the issues raised here and should you require any clarification or any further information, please do not hesitate to contact me.

Yours sincerely

PROFESSOR CHARLES MILNE
Director, Scotland

Annex 1 – FSA Response - Petition PE1376

Methanol is sequentially oxidised within the body to produce formaldehyde, formic acid or formate and finally carbon dioxide, which is excreted. A small amount of unchanged methanol is directly excreted via the kidneys or in expired air.

Methanol at high doses is known to cause toxicity, with a dose of 20-60 g or more being potentially fatal and a dose of 8 g or more being associated with adverse visual effects. The toxicity occurs when the pathway oxidising formate to carbon dioxide is saturated and the formate metabolite accumulates. Formate binds to an enzyme called cytochrome oxidase, disrupting cellular respiration, which in turn leads to a range of adverse effects, particularly in the cells of the retina and the optic nerve.

Methanol and consequently formaldehyde and formate are produced throughout the body by the enzyme protein carboxyl methylase. Formaldehyde is also produced directly through demethylation reactions and is also broken down to formate and carbon dioxide.

It is well known that aspartame breaks down into aspartic acid phenylalanine and methanol, with a maximum of 10% methanol by weight being produced. The Acceptable Daily intake for aspartame is 40 mg/kg bodyweight per day or 2400 mg for a 60 kg adult, leading to a maximum potential intake of 4 mg/kg bw or 240 mg methanol/day. UK survey data suggest that the exposure is significantly less than this. The maximum permitted level of aspartame in soft drinks is 500 mg/L, potentially releasing 50 mg/L methanol.

Methanol is also found in foods, notably fruits and vegetables and fruit juices both as free methanol (average level 140 mg/L), but it can also be produced from bacterial fermentation of pectin in the gut and then absorbed; it has been suggested that 1kg apples could produce 500 mg methanol. Formaldehyde is also found naturally in food stuffs such as fruit and vegetables, particularly mushrooms, while formate is present in honey and coffee.

It has been reported in the literature that 300-600 mg methanol is produced in the body per day. Dietary Intake of methanol has been estimated to be up to 1000 mg, though this will depend on the exact composition of the diet and the contribution from the breakdown of pectin and other large molecules. Thus the levels potentially released by aspartame are less than those produced naturally or consumed in food. The minimum toxic dose for visual effects is 8000 mg.

There is no evidence that the methanol present in food or released from pectins or released during digestion is in anyway different from any other form of methanol used as a chemical or released from aspartame. The key issue is the amount consumed, the quantities of methanol in the diet including from aspartame are not enough to saturate the formate to carbon dioxide conversion and so do not lead to the accumulation of formate, which is the cause of the observed toxicity.

When aspartame was initially approved by the UK Committee on the Toxicity of Chemicals in Food, Consumer products and the Environment (COT), it was known that methanol was produced. However, this was not considered to be of concern since the levels potentially produced were comparable to levels naturally occurring in fruit juices. Several published studies in which large quantities of aspartame (well in excess of permitted levels) are given to volunteers suggest that blood methanol and urinary formate levels temporarily increase, but blood formate does not, meaning that methanol is being produced but the body is metabolising and excreting it without the accumulation of formate, the toxic metabolite.

It is known that there are anecdotal reports of adverse health effects associated with aspartame. Whilst anecdotal evidence is useful in generating hypotheses, it has to be reproduced in properly controlled conditions to establish causality. There have been several studies which have tried to establish whether aspartame can affect neurological endpoints including, cognition, mood and behaviour, but these endpoints have not yet been reliably reproduced.